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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,392	07/10/2002	Wolf-Dieter Deckwer	930008-2069	4954

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EXAMINER	
PATTERSON, CHARLES L JR	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,392	DECKWER ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because at least four of the five sequences in Fig. 3 are not included in the sequences disclosure. The application could be examined without these sequences but the sequence must be included in the sequence disclosure.

The disclosure is objected to because of the following informalities:

The specification does not contain a Brief Description Of The Drawings, as required by 37 CFR § 1.74.

On page 12, lines 16-19, shaded amino acids and "black-rimmed box" are referred to. Figure 3 submitted with the application does not show these items.

On page 13, line 5, "GIuC" is referred to as being something that the enzyme was digested with. It is not know what "GIuC" is. Either the recitation should be omitted or else defined with a reference showing that this is the abbreviation for the substance.

Figure 7 has a legend in the figure that shows a cross-hatched box for "ester-cleaving enzyme" and a black box for "Pseudomonas sp. lipase". The figure shows cross-hatched bars and also clear bars. There are not black bars.

Appropriate correction is required.

Claims 1, 2-5, 7-8 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 12 are incorrect in the recitation of "Thermomonospora fusca" and "Pseudomonas sp., Rizomucor miehei, Candida cylindracea, Candida antartica, Aspergillus niger, Chromobacterium viscosum, Commamonas acidovarans, Rhizopus arrhizus and Rhizopus delmar", which should be "*Thermomonospora fusca*" and "*Pseudomonas sp., Rizomucor miehei, Candida cylindracea, Candida antartica, Aspergillus niger, Chromobacterium viscosum, Commamonas acidovarans, Rhizopus arrhizus and Rhizopus delmar*".

Claim 1 is indefinite in the recitation of "optionally" on line 2. It is not known whether this is meant as a limitation on the claim or is simply illustrative.

Claim 3 is indefinite in the recitation of "optionally" on line 3 and "especially" and "and/or" on line 4. In the first two instances it is not known whether this is meant to be a limitation on the claim or is simply illustrative and in the last instance it is not known whether the limitation and meant to be cumulative or in the alternative.

Claim 4 is indefinite in the recitation of the 4 parentheses. Parenthesis should be avoided in patent claims as it is not known whether the parenthetical expression is meant to be limiting on the claim or merely illustrative. In the case of the last two parentheses it is unclear whether the parenthetical expression is the optimum or range.

Claim 5 is indefinite and confusing in the recitation of "resulting from...insertion...of amino acids of SEQ ID NO:1". It is not know how amino acids "of SEQ ID NO:1" can be inserted in SEQ ID NO:1. Is applicant referring to some particular amino acids of the sequence?

Claims 7 and 8 are indefinite in the recitation of "or against a synthetic peptide or protein". Is this meant perhaps to refer to the synthetic

peptide or protein of claim 6 or to any synthetic peptide or protein whatsoever?

Claim 10 is indefinite in the recitation of "and/or" twice and "optionally". It is not known whether the limitation and meant to be cumulative or in the alternative and it is not known whether this is meant to be a limitation on the claim or is simply illustrative.

Claim 11 is indefinite in the recitation of "especially".

Claim 13 is indefinite in the recitation of "and/or" on line 3. The claim is also indefinite in the recitation of "or of a synthetic peptide...or natural compounds". The claim as it now stands reads on any synthetic peptide, etc. whatsoever since the last part of the claim is not limited to claim 1.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 and 13-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In U.S. patent practice there must be some indication of the "hand of man" in patent claims. Changing claims 1-5 to "An isolated...enzyme" or some similar recitation would overcome this rejection.

Use claims are not proper in U.S. patent practice. Claims 13-15 must be expressed as method claims with distinct steps.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

The specification does not teach that either a polyclonal or monoclonal antibody was made against the enzyme of claim 1 and certainly not against any "a synthetic peptide or protein". Neither does it teach a hybridoma cell producing the monoclonal antibody. Therefore, since the existence of the antibodies and hybridoma cell is not disclosed, it is maintained that the specification does not meet the requirements of the written description requirement of 35 USC § 112 first paragraph and furthermore it does not enable one of ordinary skill in the art to make these items since no guidance is given as to exactly how they should be made. It is maintained that there is some inventive contribution to making an antibody.

Also, the specification does not teach that a genetically modified microorganism was ever made containing the gene encoding the enzyme of claim 1 and therefore the specification does not meet the requirements of written description as to claims 16-17. To start with, the sequence of the gene encoding the enzyme must be known and the specification does not disclose this. Secondly, it is maintained that there is some inventive contribution involved in the cloning of the enzyme gene. Therefore the specification does not

teach one of ordinary skill in the art how to make the genetically modified microorganisms of claims 16-17. Furthermore it is maintained that the inclusion of the subject matter of claims 16-17 is not supported by the specification as filed and therefore is new matter and must be deleted, absent convincing proof to the contrary.

Claims 5-6 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to "a mutant or derivative of SEQ ID NO:1 resulting from substitution, insertion or deletion of amino acids of SEQ ID NO:1, and wherein said mutant or derivative has ester-group-cleaving enzyme activity", "a part of the sequence" of claim 5 and the "[u]se...of a synthetic peptide or protein or of an ester-group-cleaving composition for the degradation of ester-group-containing low molecular weight and/or macromolecular synthetic or natural compounds". The specification does not teach one of ordinary skill in the art to how to produce a mutant of SEQ ID NO:1 having enzymatic activity. It does not discuss what sites in SEQ ID NO:1 must be present nor which sites are less important for activity. It certainly does not teach one to make "a part of the sequence" that has activity. Furthermore, the specification does not teach one of ordinary skill in the art to use <u>any</u> synthetic peptide or protein or <u>any</u> ester-group-cleaving composition to degrade an ester-group-containing compounds and certainly not <u>any and all</u> "natural compounds". Therefore the instant specification does not teach one of ordinary skill in the art to make the embodiments of the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 10-15 are rejected under 35 U.S.C. 102(a or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either of Kellis, et al. (A), Hollick (U), Kleeberg, et al. (V) or Fett, et al. (W). Kellis, et al. teach at least in column 6, lines 42-67 that polyesterases may be isolated from *Thermomonospora spp.*. Hollick teaches in at least Table 3, page 191 that *Thermomonospora fusca* produces an esterase, an esterase-lipase and a lipase. Kleeberg, et al. teach that *Thermomonospora fusca* produces a enzyme that will degrade aliphatic-aromatic copolymers. Fett, et al. teach the *Thermomonospora fusca* produces an enzyme that hydrolyzes cutin, which is in the Introduction is taught to be "C_{16} to C_{18}

hydroxy- and epoxyfatty acids held together via ester bonds". It is maintained that the enzymes taught by the instant references are the same as that of the instant claims, absent very convincing proof to the contrary. It is noted that claim 1 says that the enzyme is "obtainable by culturing...Thermomonospora fusca", not that it is obtained from Thermomonospora fusca. The patent office does not have the facilities to test whether claimed enzymes are the same as those in prior art references and this testing is left to applicants. It would have been obvious to isolate and purify the enzyme and to add other enzymes, stabilizers, etc. absent unexpected results. It is noted that claim 10 says that some of these substances are "optionally" added.

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kellis, et al. (A), Hollick (U), Kleeberg, et al. (V) or Fett, et al. (W) in view of Goldwasser, et al (B). The primary references are characterized *supra*. Goldwasser, et al. teach how to produce polyclonal and monoclonal antibodies and hybridomas from a protein. It would have been obvious to one of ordinary skill in the art to obtain the enzyme taught by the primary references and to use this protein to produce antibodies according to Goldwasser, et al., absent unexpected results.

Hollick (U) is listed on the PCT search report and Kleeberg, et al. (V) is by three of the inventors of this application and therefore copies of the references are not being sent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
May 27, 2004